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09/879,480	06/12/2001	Jack C. Whittier	HrdMgmtCIP	6452
7590 10/03/2003 Santangelo Law Offices, P.C. Third Floor 125 South Howes Fort Collins, CO 80521			EXAMINER MYERS, CARLA J	
			ART UNIT 1634	PAPER NUMBER

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<p style="text-align: center;"><b>Office Action Summary</b></p>	<p><b>Application No.</b></p> <p>09/879,480</p>	<p><b>Applicant(s)</b></p> <p>WHITTIER ET AL.</p>	
	<p><b>Examiner</b></p> <p>Carla Myers</p>	<p><b>Art Unit</b></p> <p>1634</p>	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other:  |

### **DETAILED ACTION**

1. In the information disclosure statement filed June 12, 2001, the references to US applications have been crossed off because copending U.S. applications are not appropriately listed in information disclosure statements. However, these copending applications have been considered by the Examiner. References in which Applicants supplied only the table of contents have not been considered, including Amann (1982), Ginther (1992), Meilgarrrd (1991; index of terms only), Pickett (1989), Sell, and Squires (1999). The Lindsey reference has been lined through because it does not include a publication source or a publication date, as is required under 37 CFR § 1.98. The Linge (1972) reference has not been considered because Applicant did not provide a concise statement of the relevance of this non-English language reference listed, as required under 37 CFR § 1.98(a)(3).

### **Specification**

2. The disclosure is objected to because of the following informalities:

Throughout the specification, numbers are used to refer to references. However, the references corresponding to these numbers are not provided in the specification. Accordingly, it is unclear as to what references Applicant's are citing. The specification should be amended to delete these reference numbers.

### **Priority**

Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional applications upon which priority is claimed were filed greater than one year prior to the filing of U.S. Application No.

09/744,675, filed January 29, 2001. Accordingly, priority has not been granted to the stated provisional applications. Furthermore, it is noted that the subject matter of the present claims is entitled to priority only to the instant filing date of June 12, 2001. A claim as a whole is assigned an effective filing date rather than the subject matter within a claim being assigned individual effective filing dates. The priority applications do not disclose the general concept of a method of managing animals by inseminating a female of a species of mammal with an artificial insemination sample having a plurality of spermatozoa wherein at least 90% of said plurality of spermatozoa have a sex determination characteristic corresponding to the same sex of an offspring mammal.**Claim Rejections - 35**

#### **USC § 112**

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of producing bovine offspring wherein the methods comprise inseminating a female bovine with an insemination sample having a plurality of spermatozoa wherein the spermatozoa have been purified to the extent that up to 90% of the spermatozoa have X-bearing chromosomes or wherein up to 90% of the spermatozoa have Y-bearing chromosomes, and while the prior art (Buchanan 2000) has enabled methods of producing equine offspring wherein the methods comprise inseminating a female equine with an insemination sample having a plurality of spermatozoa wherein up

to 90% of the spermatozoa have an X chromosome, and while the prior art (Rens US Patent No. 5,985,216, issued November 16, 1999) has enabled methods of producing porcine offspring wherein the methods comprise inseminating a female porcine with an insemination sample having a plurality of spermatozoa wherein up to 92% of the spermatozoa have an Y chromosome, does not reasonably provide enablement for methods of managing any animal by artificial insemination using an insemination sample having a plurality of spermatozoa wherein up to 100% of the spermatozoa have the same sex determination characteristic and wherein up to 100% male or female offspring are produced. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The following factors have been considered in formulating this rejection (*In re Wands*, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988): the breadth of the claims, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, the amount of direction or guidance presented, the presence or absence of working examples of the invention and the quantity of experimentation necessary.

The claims are drawn broadly to methods of managing an animal by producing a female of a species of mammal, inseminating said female with an artificial insemination sample wherein the sample includes at least 90% of spermatozoa that have the same sex determination characteristic, fertilizing at least one egg of said female and producing an offspring mammal. The claims

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further include producing offspring mammals that comprise 90% or more male offspring and 90% or more female offspring.

Case law has established that “(t)o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without ‘undue experimentation.’” *In re Wright* 990 F.2d 1557, 1561. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) it was determined that “(t)he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art”. Furthermore, the Court in *Genetech Inc. v Novo Nordisk* 42 USPQ2d 1001 held that “(l)it is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of the invention in order to constitute adequate enablement”. In the instant case, specification has not adequately taught one of skill in the art how to practice methods of enriching spermatozoa to purities of 100% in bovine mammals or to purities of 90% or greater in all animals for the following reasons.

The specification at page 6 makes clear that the claimed invention is not intended to be limited to bovine animals. Rather, the claimed invention is applicable “to a variety of species of mammal including, but not limited to, humans, bovids, equids, ovids, canids, goats or swine, as well as less commonly known animals such as elephants, zebra, camels, or kudu...As such, the examples provided are not intended to limit the description of the invention to the management of any particular specie(s) of mammal(s).” Accordingly, Applicant’s claims are intended to include the management of human populations by

controlling the sex of offspring, the number of offspring and the size of the population. In particular, claim 14 includes inducing early puberty in a human female; claim 18 includes early weaning of a human; claim 21 includes synchronizing estrous in a human population; claim 23 includes "harvesting said female of said species of mammal" wherein said mammal includes a human. In addition to the clear concerns associated with the harvesting of human beings and the managing of human populations by inducing early puberty in human females, the specification has not enabled the use of such methods in humans. Applicants have not adequately taught any methods of inducing early puberty in a human female and have not taught how a human treated in the above manners could then be used to effectively produce offspring that could be "managed." While the specification states that "Diet is an effective tool to induce puberty" (see page 2), it is not clear as to whether this statement is intended to refer only to bovines. There are no teachings in the specification as to the use of controlling diet as a means of inducing early puberty in human females. Lacking any guidance from the specification as to how one would specifically induce early puberty in a human female and then use this female for reproductive purposes, one of skill in the art would not be able to practice this aspect of the claimed invention. Furthermore, the specification does not make clear as to whether modification of diet so as to cause a specified weight gain induces early puberty in animals other than cattle, such as equine, rabbits, elephants, goats and zebras. The specification does not specifically discuss methods for inducing early puberty in non-bovine animals.

Secondly, the ability to sort sperm from any animal on the basis of a "sex determination characteristic" such that the resulting sample contains more than 90% of sperm having the same sex determination characteristic and to reproducibly generate offspring in which 90% or more of the offspring are male or in which 90% or more of the offspring are female is highly unpredictable. This unpredictability is exemplified by the results set forth in the specification. In particular, pages 40-41 of the specification states:

"Eleven of 16 (69%) calves conceived from semen sorted for X-chromosome were female and all three calves conceived from non-sexed semen were bulls (100%), whereas the only female born to natural serve was female (100%). Seidel et al. (87) reported that 86% of calves conceived from sexed semen are of the desired sex. The result of this data set of 69% of calves conceived from sexed semen were of desired sex, is not an adequate replication of their study as too few individuals were used. The low percent of desired sex was not expected as the true percent of X-chromosome sperm varied from 86-92% for the batches of semen used in the study."

Applicants fail to provide any examples in which semen is sorted to rates above 86-92% and fail to teach how the methodology set forth within the specification could be modified to achieve the production of animals in which more than 69% of the animals of one "desired" sex. The prior art of Rens (US Patent 5,985,216, issued 1999) does teach that bovine sperm can be sorted to purities of about 90%. Rens also teaches that under some conditions, porcine sperm could be sorted to a purity of 92% for sperm bearing the Y chromosome. In addition, Buchanan (April 2000, page 1337) teaches methods for sorting equine sperm wherein the sperm were successfully sorted to a purity of 90% for



sperm bearing the X chromosome and to 84% for sperm bearing the Y chromosome. However, there is no specific guidance provided in the specification for how one may accomplish the sexing of sperm to achieve purity rates of 95%, 99% or 100% in bovine animals, in humans or in any other animal. It is unpredictable as to whether one of skill in the art could sort sperm from any animal at purity rates of 90% or above and generate populations of animals in which 90% or more of the offspring are of the same sex. The unpredictability of sorting sperm to high levels of purity, including purity levels above 90% is supported by the teachings in the art. For example, Fugger (1999; cited in the IDS of 6/12/01) teach that using the most current techniques, human sperm cells can be separated to provide samples containing on average 88% enrichment for X-bearing sperm and 69% enrichment for Y-bearing sperm (see page 1439). Fugger goes on to state that :

"Human sperm cells present unique characteristics that affect the ability to detect and separate X and Y sperm by flow cytometry. The current flow technology appears to be most efficient with sperm cells that have a substantial difference in total DNA, are relatively homogeneous with respect to physical shape and cellular morphology, and are more paddle shaped to take advantage of flow-induced orientation before fluorescence detection. Most human sperm, however, are heterogeneous, vary substantially within and between individuals, are oval in shape, vary in the magnitude of difference in DNA content between X and Y chromosomes due to individual variation in size of the Y chromosome, and contain a relatively small 2.8% difference in total DNA content compared to >3.5% for most domestic animals."

Additionally, Johnson (1992, page 13; cited in the IDS of 6/12/01) teach the difference in DNA content between X and y chromosome bearing sperm for

several organisms, including turkey (0% difference), human (2.9% difference) and rabbit (3% difference). Johnson also reports that rabbit sperm were sorted to purities of 86% for X-chromosome bearing sperm and 81% for Y-chromosome bearing sperm.

However, there are no teachings in the prior art as to how to overcome the problems associated with a lack of difference in the DNA content between X and Y-chromosome bearing sperm or the challenges imposed by the shape, morphology and heterogeneity of sperm. The specification and prior art do not appear to exemplify any methods in which sperm from non-bovine animals are reproducibly purified to 90% or higher purity for both X and Y-chromosome bearing sperm in the majority of species of animals or mammals. The specification does not provide sufficient guidance as to which animal species have sperm which can be sorted to high purity levels and has not taught one of skill in the art what methodologies should be used to sort sperm from non-bovine animals to purity levels of 90% or above. Additionally, the specification does not provide sufficient guidance to enable the skilled artisan to sort sperm from bovine animals to purity levels of 95%-100%. It is unpredictable as to what methodologies should be employed to achieve these high purity levels and to produce offspring in which 90% or more of the offspring are of the same desired sex.

In view of the unpredictability in the art and the lack of specific guidance provided in the specification, undue experimentation would be required to practice the invention as it is broadly claimed.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 1-27 are indefinite because it is not clear as to what is intended to be encompassed by a method of managing animals. The claims are drawn to a method of managing animals. However, the final process step is one of producing an offspring mammal. The claims do not clarify how the step of producing an offspring mammal results in the management of animals. Accordingly, it is unclear as to whether the concept of managing animals is intended to include only producing an offspring mammal or is intended to include some other means of controlling an animal population. Furthermore, it is unclear as to whether the claims are intended to be limited to methods which involve any animal or methods which involve only mammals.

B. Claim 10 is indefinite because the claim refers to the use of frozen-thawed spermatozoa. However, claim 6 from which claim 10 depends is limited to methods which use non-frozen spermatozoa.

C. Claim 11 is indefinite over the recitation of "a typical number of spermatozoa." There is no fixed definition in the art for what constitutes a typical number of spermatozoa for the artificial insemination of all animals and this phrase has not been clearly defined in the specification. Accordingly, one could not determine the meets and bounds of the claimed invention.

D. Claims 12 and 13 are indefinite over the recitations of “the percentage of male offspring mammals” and “the percentage of female offspring mammals” because these phrases lack antecedent basis. The claims previously refer to producing **an** offspring mammal, but do not refer to percentages or to male or female offspring mammals.

E. In claims 16 and 17, the phrase “said female of said bovine species” lacks proper antecedent basis.

F. Claim 19 is indefinite and confusing over the recitation of “wherein said female of said species of mammal comprises said female of said bovine species of mammal.” It is unclear as to what is intended to be the distinction between or the relationship between the female of said species of mammal and the female of said bovine species of mammal. How does a species of mammals comprise a bovine species of mammals? Furthermore, “said female of said bovine species of mammal” lacks proper antecedent basis. Additionally, in claim 20 the phrase “said bovine species of mammal” also lacks antecedent basis.

G. Claim 26 is indefinite over the phrase of “replacing said female of said species of mammal with said offspring mammal” because it is not clear as to what is meant by replacing and it is not clear as to how this step relates back to the method of managing animals.

H. Claim 27 is indefinite over the recitation of “said male offspring mammal” because this phrase lacks proper antecedent basis.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6, 9, 11 are rejected under 35 U.S.C. 102(b) and 102(e) as being anticipated by Rens et al (US Patent No. 5,985,216; cited in the IDS of 6/12/01).

Rens et al teach a method which includes the steps of: a) producing a female bovine mammal; b) inseminating said female bovine mammal with a sample containing sorted sperm at a purity of 90% for X and Y sorted sperm; c) fertilizing at least one egg within the mammal; and d) producing an offspring mammal. Since Rens teaches a method which includes each of the steps of the claimed method, the method of Rens is considered to necessarily be one which manages animals.

With respect to claims 6 and 9, Rens (column 7) teaches using 4 to 5 million sperm for each artificial insemination. With respect to claim 11, since the claims and specification do not define what is intended to be included by a typical number of spermatozoa, the quantity of spermatozoa utilized by Rens is considered to comprise from about 10% to about 50% of the typical amount of spermatozoa.

7. Claims 1-6, 9, and 11-13 are rejected under 35 U.S.C. 102(a) and 102(b) as being anticipated by Seidel (December 1997, Theriogenology, Vol. 48; cited in the IDS of 6/12/01).

Seidel et al (page 1261-1262) teach a method which includes the steps of: a) producing a female bovine mammal; b) inseminating said female bovine mammal with a sample containing sorted sperm at a purity of about 90% for X and Y sorted sperm; c) fertilizing at least one egg within the mammal; and d) producing an offspring mammal. Since Seidel teaches a method which includes each of the steps of the claimed method, the method of Seidel is considered to necessarily be one which manages animals.

With respect to claims 6 and 9, Seidel teaches using  $1-2.5 \times 10^5$  sorted live sperm for each artificial insemination. With respect to claim 13, Seidel teaches that 100% of the offspring from X-sorted sperm were female and 75% of the offspring from Y sorted sperm were males (see page 1262). With respect to claim 11, since the claims and specification do not define what is intended to be included by a typical number of spermatozoa, the quantity of spermatozoa utilized by Seidel is considered to comprise from about 10% to about 50% of the typical amount of spermatozoa.

8. Claims 1-5, and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Johnson (Reprod. Fertil. Dev. (1995) 7: 893-903; cited in the IDS of 6/12/01).

Johnson (see abstract and pages 898 and 891) teaches a method which includes the steps of: a) producing a female bovine mammal; b) inseminating said female bovine mammal with a sample containing sorted sperm

at a purity of 90% for X and Y sorted sperm; c) fertilizing at least one egg within the mammal; and d) producing an offspring mammal. Since Johnson teaches a method which includes each of the steps of the claimed method, the method of Johnson is considered to necessarily be one which manages animals. With respect to claim 12, Johnson teaches that 90% of the offspring from Y sorted sperm were male.

9. Claims 1-2, 4, 8, 11 and 13 are rejected under 35 U.S.C. 102(a) or 102(b) as being anticipated by Buchanan (Theriogenology (April 2000) 53: 1333-1344; cited in the IDS of 6/12/01).

Buchanan (page 1337-1338) teaches a method which includes the steps of: a) producing a female equine mammal; b) inseminating said female bovine mammal with a sample containing sorted sperm at a purity of 90% for X sorted sperm; c) fertilizing at least one egg within the mammal; and d) producing an offspring mammal. Since Buchanan teaches a method which includes each of the steps of the claimed method, the method of Buchanan is considered to necessarily be one which manages animals.

With respect to claim 11, since the claims and specification do not define what is intended to be included by a typical number of spermatozoa, the quantity of spermatozoa utilized by Buchanan is considered to comprise from about 10% to about 50% of the typical amount of spermatozoa. With respect to claim 13, Buchanan teaches that 100% of the offspring from X sorted sperm were female.

***Claim Rejections - 35 USC § 103***

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10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rens in view of Seidel (1995; abstract 513, 'Insemination of heifers with very low numbers of frozen spermatozoa,' cited in the IDS of 6/12/01).

Rens et al teach a method which includes the steps of: a) producing a female bovine mammal; b) inseminating said female bovine mammal with a sample containing sorted sperm at a purity of 90% for X and Y sorted sperm; c) fertilizing at least one egg within the mammal; and d) producing an offspring mammal. Since Rens teaches a method which includes each of the steps of the



claimed method, the method of Rens is considered to necessarily be one which manages animals. Rens teaches inseminating female bovine with non-frozen sperm, but does not teach using frozen-thawed sperm.

Seidel teaches the effective insemination of heifers with thawed frozen sperm. The reference teaches that no differences were observed when using  $1 \times 10^5$  versus  $10 \times 10^6$  sorted sperm.

In view of the teachings of Seidel, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Rens so as to have used thawed-frozen sperm because this would have provided a more convenient means for managing the animals since the frozen sperm could be sorted and stored prior to its use for artificial insemination.

11. Claims 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rens.

Rens et al teach a method which includes the steps of: a) producing a female bovine mammal; b) inseminating said female bovine mammal with a sample containing sorted sperm at a purity of 90% for X and Y sorted sperm; c) fertilizing at least one egg within the mammal; and d) producing an offspring mammal. Since Rens teaches a method which includes each of the steps of the claimed method, the method of Rens is considered to necessarily be one which manages animals. Rens does not teach that the offspring produced are at least 70% male offspring for the Y sorted sperm or at least 70% female for the X sorted sperm. However, it would have been expected that sperm sorted to a

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purity of about 90% would produce offspring that were at least 70% male and 70% female for the Y and X sorted sperm respectively.

12. Claims 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rens in view of Hall (1997; cited in the IDS of 6/12/01).

Rens et al teach a method which includes the steps of: a) producing a female bovine mammal; b) inseminating said female bovine mammal with a sample containing sorted sperm at a purity of 90% for X and Y sorted sperm; c) fertilizing at least one egg within the mammal; and d) producing an offspring mammal. Since Rens teaches a method which includes each of the steps of the claimed method, the method of Rens is considered to necessarily be one which manages animals. Rens does not teach inducing early puberty in the animal to be inseminated.

Hall teaches inducing early puberty in heifers by causing a rapid weight gain then a slow weight gain for heifers at ages 6.5 months to 12.5 months (see for example page 1607). Hall teaches that inducing puberty is a means for managing animals so as to enhance their reproductive efficiency.

In view of the teachings of Hall, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Rens so as to have induced early puberty in the female bovines that were to be inseminated in order to have achieved the advantage set forth by Hall of enhancing their reproductive efficiency.

13. Claims 18-20 and 23-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rens in view of Hall and further in view of Grimes(1991; cited in the IDS of 6/12/01).

The teachings of Rens and Hall are presented above. The combined references do not teach early weaning of the female. However, Grimes (pages 468 and 471) teaches methods in which calves are weaned at 110 or 222 days. Grimes teaches that early weaned calves consumed less food and thereby provide an economic advantage. Grimes also teaches harvesting the animals prior to 24 months (Table 3). At pages 471, Grimes states: "Early weaning could be used in an integrated production system to expedite the finishing phase and to slaughter younger animals. It also could be used to accelerate development of females who are to be placed into the breeding herd, thus allowing these females to be bred younger."

In view of the teachings of Grimes, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Rens so as to have weaned the calves early in order to have provided the advantage set by Grimes of provide a more economical method for managing cows. Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have harvested the male offspring and female mammal in order to have provided a more effective means for managing the animals and for the economical advantages set forth by Grimes.

14. Claims 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rens in view of Hall and Grimes and further in view of Deutscher (cited in the IDS of 6/12/01).

The teachings of Rens, Hall and Grimes are presented above. The combined references do not teach synchronizing estrous in the female mammal. However, Deutscher teaches synchronizing estrous by dressing animal feed with 0.5 mg MGA for 14 days and injecting PGF at 19 days following the last MGA feeding (see page 165). The reference teaches that this method of synchronizing heifers results in an increased pregnancy rate (see page 164).

In view of the teachings of Deutscher, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Rens so as to have synchronized estrous in the heifers in order to have achieved the advantage set forth by Deutscher of increasing the pregnancy rates and thereby providing a more economical method for managing cows.

15. Claims 7 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seidel (1997) in view of Seidel (1995; abstract 513, 'Insemination of heifers with very low numbers of frozen spermatozoa,' cited in the IDS of 6/12/01).

Seidel et al (page 1261-1262) teach a method which includes the steps of: a) producing a female bovine mammal; b) inseminating said female bovine mammal with a sample containing sorted sperm at a purity of about 90% for X and Y sorted sperm; c) fertilizing at least one egg within the mammal; and d) producing an offspring mammal. Since Seidel teaches a method which includes each of the steps of the claimed method, the method of Seidel is considered to

necessarily be one which manages animals. Seidel teaches using  $1-2.5 \times 10^5$  sorted live sperm for each artificial insemination. Seidel also states that the use of low doses of frozen semen show considerable promise for commercial applications (see page 1262). However, Seidel does not exemplify a method of using frozen-thawed sperm.

Seidel (1995) teaches the effective insemination of heifers with thawed frozen sperm. The reference teaches that no differences were observed when using  $1-5 \times 10^5$  versus  $10 \times 10^6$  sorted sperm.

In view of the teachings of Seidel (1995), it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Seidel so as to have used thawed-frozen sperm because this would have provided a more convenient means for managing the animals since the frozen sperm could be sorted and stored prior to its use for artificial insemination making this sperm more applicable for commercial use.

16. Claims 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seidel (1997) in view of Hall (1997; cited in the IDS of 6/12/01).

Seidel et al (page 1261-1262) teach a method which includes the steps of:  
a) producing a female bovine mammal; b) inseminating said female bovine mammal with a sample containing sorted sperm at a purity of about 90% for X and Y sorted sperm; c) fertilizing at least one egg within the mammal; and d) producing an offspring mammal. Since Seidel teaches a method which includes each of the steps of the claimed method, the method of Seidel is considered to

necessarily be one which manages animals. Seidel does not teach inducing early puberty in the animal to be inseminated.

Hall teaches inducing early puberty in heifers by causing a rapid weight gain then a slow weight gain for heifers at ages 6.5 months to 12.5 months (see for example page 1607). Hall teaches that inducing puberty is a means for managing animals so as to enhance their reproductive efficiency.

In view of the teachings of Hall, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Seidel so as to have induced early puberty in the female bovines that were to be inseminated in order to have achieved the advantage set forth by Hall of enhancing their reproductive efficiency.

17. Claims 18-20 and 23-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seidel (1997) in view of Hall and further in view of Grimes(1991; cited in the IDS of 6/12/01).

The teachings of Seidel, Hall and Grimes are presented above. The combined references do not teach early weaning of the female. However, Grimes (pages 468 and 471) teaches methods in which calves are weaned at 110 or 222 days. Grimes teaches that early weaned calves consumed less food and thereby provide an economic advantage. Grimes also teaches harvesting the animals prior to 24 months (Table 3). At pages 471, Grimes states: "Early weaning could be used in an integrated production system to expedite the finishing phase and to slaughter younger animals. It also could be used to

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accelerate development of females who are to be placed into the breeding herd, thus allowing these females to be bred younger.”

In view of the teachings of Grimes, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Seidel so as to have weaned the calves early in order to have provided the advantage set by Grimes of provide a more economical method for managing cows. Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have harvested the male offspring and female mammal in order to have provided a more effective means for managing the animals and for the economical advantages set forth by Grimes.

18. Claims 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seidel (1997) in view of Hall and Grimes and further in view of Deutscher (cited in the IDS of 6/12/01).

The teachings of Seidel, Hall and Grimes are presented above. The combined references do not teach synchronizing estrous in the female mammal. However, Deutscher teaches synchronizing estrous by dressing animal feed with 0.5 mg MGA for 14 days and injecting PGF at 19 days following the last MGA feeding (see page 165). The reference teaches that this method of synchronizing heifers results in an increased pregnancy rate (see page 164).

In view of the teachings of Deutscher, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Seidel so as to have synchronized estrous in the heifers in order to

have achieved the advantage set forth by Deutchser of increasing the pregnancy rates and thereby providing a more economical method for managing cows.

19. Claims 7, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson in view of Seidel (1995; abstract 513, 'Insemination of heifers with very low numbers of frozen spermatozoa,' cited in the IDS of 6/12/01).

Johnson (see abstract and pages 898 and 891) teaches a method which includes the steps of: a) producing a female bovine mammal; b) inseminating said female bovine mammal with a sample containing sorted sperm at a purity of 90% for X and Y sorted sperm; c) fertilizing at least one egg within the mammal; and d) producing an offspring mammal. Since Johnson teaches a method which includes each of the steps of the claimed method, the method of Johnson is considered to necessarily be one which manages animals. Johnson does not teach using frozen-thawed sperm for insemination purposes.

Seidel teaches the effective insemination of heifers with thawed frozen sperm. The reference teaches that no differences were observed when using  $1 \times 10^5$  versus  $10 \times 10^6$  sorted sperm.

In view of the teachings of Seidel, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Johnson so as to have used thawed-frozen sperm because this would have provided a more convenient means for managing the animals since the frozen sperm could be sorted and stored prior to its use for artificial insemination. With respect to claim 11, since the claims and specification do not define what is



intended to be included by a typical number of spermatozoa, the quantity of spermatozoa utilized by modifying the method of Johnson as described above is considered to comprise from about 10% to about 50% of the typical amount of spermatozoa.

20. Claims 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson.

Johnson et al teach a method which includes the steps of: a) producing a female bovine mammal; b) inseminating said female bovine mammal with a sample containing sorted sperm at a purity of 90% for X and Y sorted sperm; c) fertilizing at least one egg within the mammal; and d) producing an offspring mammal. Since Johnson teaches a method which includes each of the steps of the claimed method, the method of Johnson is considered to necessarily be one which manages animals. Johnson (table 2) teaches that 90% of the offspring from Y sperm were males. Johnson does not teach that the offspring produced are at least 70% female for the X sorted sperm. However, it would have been expected that sperm sorted to a purity of about 90% would produce offspring that were at least 70% male and 70% female for the Y and X sorted sperm respectively.

21. Claims 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson in view of Hall (1997; cited in the IDS of 6/12/01).

The teachings of Johnson are presented above. Johnson does not teach inducing early puberty in the animal to be inseminated.

Hall teaches inducing early puberty in heifers by causing a rapid weight gain then a slow weight gain for heifers at ages 6.5 months to 12.5 months (see for example page 1607). Hall teaches that inducing puberty is a means for managing animals so as to enhance their reproductive efficiency.

In view of the teachings of Hall, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Johnson so as to have induced early puberty in the female bovines that were to be inseminated in order to have achieved the advantage set forth by Hall of enhancing their reproductive efficiency.

22. Claims 18-20 and 23-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson in view of Hall and further in view of Grimes(1991; cited in the IDS of 6/12/01).

The teachings of Johnson and Hall are presented above. The combined references do not teach early weaning of the female. However, Grimes (pages 468 and 471) teaches methods in which calves are weaned at 110 or 222 days. Grimes teaches that early weaned calves consumed less food and thereby provide an economic advantage. Grimes also teaches harvesting the animals prior to 24 months (Table 3). At pages 471, Grimes states: "Early weaning could be used in an integrated production system to expedite the finishing phase and to slaughter younger animals. It also could be used to accelerate development of females who are to be placed into the breeding herd, thus allowing these females to be bred younger."

In view of the teachings of Grimes, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Johnson so as to have weaned the calves early in order to have provided the advantage set by Grimes of provide a more economical method for managing cows. Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have harvested the male offspring and female mammal in order to have provided a more effective means for managing the animals and for the economical advantages set forth by Grimes.

23. Claims 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson in view of Hall and Grimes and further in view of Deutscher (cited in the IDS of 6/12/01).

The teachings of Johnson, Hall and Grimes are presented above. The combined references do not teach synchronizing estrous in the female mammal. However, Deutscher teaches synchronizing estrous by dressing animal feed with 0.5 mg MGA for 14 days and injecting PGF at 19 days following the last MGA feeding (see page 165). The reference teaches that this method of synchronizing heifers results in an increased pregnancy rate (see page 164).

In view of the teachings of Deutscher, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Johnson so as to have synchronized estrous in the heifers in order to have achieved the advantage set forth by Deutchser of increasing the pregnancy rates and thereby providing a more economical method for managing cows.

24. Claims 6, 9 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson in view of Seidel (1995, abstract 488 "Insemination of Holstein heifers with very low numbers of unfrozen spermatozoa"; cited in the IDS of 6/12/01).

The teachings of Johnson are presented above. Johnson does not teach the quantity of non-frozen sperm used for insemination.

Seidel teaches the effective insemination of heifers with non-frozen sperm. The reference using  $1-2.5 \times 10^5$  versus  $2.5 \times 10^6$  non-frozen sperm/inseminate. Seidel teaches that using these methods it may be possible to reduce sperm numbers per inseminate so as to enhance the use of sorted sperm for commercial applications.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the non-frozen sperm of Seidel in the method of Johnson because the non-frozen sperm would have been expected to have a higher viability as compared to frozen sperm and would have allowed for the use of less sperm/inseminate thereby improving the commercial application of the insemination process. With respect to claim 11, since the claims and specification do not define what is intended to be included by a typical number of spermatozoa, the quantity of spermatozoa utilized by modifying the method of Johnson as described above is considered to comprise from about 10% to about 50% of the typical amount of spermatozoa.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is

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(703) 308-2199. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119. Papers related to this application may be faxed to Group 1634 via the PTO Fax Center using the fax number (703)-872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Carla Myers  
September 30, 2003

  
CARLA J. MYERS  
PRIMARY EXAMINER